IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al. v. AMERICAN HOME PRODUCTS CORPORATION	)	CIVIL ACTION NO. 99-20593
	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8898

Bartle, J. June 20, 2012

Sharon K. Lay ("Ms. Lay" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In May, 2000, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Charles F. Dahl, M.D. Dr. Dahl is no stranger to this litigation. According to the Trust, he has attested to at least 380 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated May 27, 1998,[3] Dr. Dahl attested in Part II of Ms. Lay's Green Form that she suffered from severe aortic regurgitation and pulmonary hypertension secondary to severe aortic regurgitation.[4]

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2. (...continued)
not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Claimant also submitted an echocardiogram dated November 24, 1998 in support of her claim.

4. Dr. Dahl also attested that claimant suffered from mild
(continued...)

Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $486,424.[5]

In the report of claimant's echocardiogram, the reviewing cardiologist, Rodney S. Badger, M.D., stated that claimant had "moderate aortic insufficiency." Dr. Badger, however, did not specify a percentage as to the level of claimant's aortic regurgitation. Under the definition set forth in the Settlement Agreement, severe aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view if the parasternal long-axis view is unavailable) is greater than 49% of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement §§ I.22. and IV.B.2.c.(2)(a).

In April, 2002, pursuant to the Policies and Procedures for Audit and Disposition of Matrix Claims in Audit ("Audit Policies and Procedures"), approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002), claimant was given an opportunity to submit additional materials in support of her claim. Ms. Lay submitted a letter from Stephen Raskin, M.D., who stated:

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4. (...continued)
mitral regurgitation. This condition is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the aortic valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of three complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(a). Pulmonary hypertension secondary to severe aortic regurgitation is one of the complicating factors needed to qualify for a Level II claim.

> Upon my reading of Ms. Lay's 5/27/98 [echocardiogram], in the parasternal long axis view, I found the JH/LVOT [sic] to be in the range of 40%-50%, which is moderate to severe aortic regurgitation. However, it is important to note that the Nyquist setting on this view was 77 cm/sec., which is significantly higher than the setting typically used. This higher setting is likely to make the regurgitant jet appear narrower and with a more typical Nyquist setting, the jet would likely appear to be in excess of 50% JH/LVOT [sic].

In July, 2002, the Trust forwarded the claim for review by Keith B. Churchwell, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Churchwell concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had severe aortic regurgitation because her echocardiogram demonstrated only mild aortic regurgitation. Dr. Churchwell explained, "By [echocardiogram] report from 11/24/98, mild [aortic insufficiency] is present by Singh criteria. Also no significant regurgitant volume is seen in the descending aorta which is [consistent with] mild disease."

Based on Dr. Churchwell's finding that claimant had mild aortic regurgitation, the Trust issued a post-audit determination denying Ms. Lay's claim. Pursuant to the Audit Policies and Procedures, claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2457, Audit Policies and Procedures § IV.C. The Trust then applied to the court for issuance of an Order to show cause why Ms. Lay's claim should be

paid. On February 28, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7011 (Feb. 28, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 1, 2007. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor[6] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedure § VI.J. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. § VI.O.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had severe aortic regurgitation. See id. § VI.D.

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6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had severe aortic regurgitation. Specifically, with respect to claimant's May 27, 1998 echocardiogram, Dr. Vigilante explained that:

> The parasternal long axis view was appropriate for evaluation of the aortic regurgitant jet. Visually, moderate aortic regurgitation was present on this study. I digitized those cardiac cycles in the parasternal long-axis view in which the aortic regurgitation was best appreciated. I then measured the JH and LVOTH with electronic calipers. The largest representative JH on this study was 0.6 cm. The LVOTH was 1.9 cm. Therefore, the largest representative JH/LVOTH ratio was 32% qualifying for moderate aortic regurgitation. This ratio never came close to approaching 50%. Most of the JH/LVOTH ratios were less than 30%.

With respect to claimant's November 24, 1998 echocardiogram, Dr. Vigilante observed that:

> The parasternal long-axis view was appropriate for evaluation of aortic regurgitation. Visually, mild aortic regurgitation appeared to be present. I

> digitized those cardiac cycles in the parasternal long-axis view in which the aortic regurgitant jet was best identified. I then measured the JH and LVOTH by electronic calipers. I determined that the largest representative JH was 0.3 cm and the LVOTH was 1.9 cm. Therefore, the largest representative JH/LVOTH ratio was 16% qualifying for mild aortic regurgitation. This ratio did not approach 25%. Most of the JH/LVOTH ratios were less than 15%.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. Claimant does not adequately refute the findings of the auditing cardiologist or the Technical Advisor that neither of Ms. Lay's echocardiograms demonstrated severe aortic regurgitation. Specifically, Dr. Churchwell and Dr. Vigilante determined that claimant's November 24, 1998 echocardiogram only demonstrated mild aortic regurgitation and Dr. Vigilante determined that claimant's May 27, 1998 echocardiogram demonstrated only moderate aortic regurgitation. Mere disagreement with the auditing cardiologist or the Technical Advisor without identifying any specific error by them is insufficient to meet a claimant's burden of proof.[7]

In addition, contrary to claimant's contention, Dr. Raskin's letter does not provide a reasonable medical basis for the attesting physician's representation that Ms. Lay had severe aortic regurgitation. As an initial matter, Dr. Raskin observed that Ms. Lay's aortic regurgitation was "in the range of

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7. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Policies and Procedures VI.N.

40% to 50%, which is moderate to severe aortic regurgitation." The Settlement Agreement specifically requires the JH/LVOTH ratio to be greater than 49%. See Settlement Agreement §§ I.22. & IV.B.2.c.(2)(a)I). In addition, Dr. Raskin's reliance on the apical long-axis view was improper. Although Dr. Raskin states that the Nyquist setting in the May 27, 1998 echocardiogram is "significantly higher than the setting typically used" and therefore not diagnostic of claimant's true level of aortic regurgitation, Dr. Vigilante determined that the parasternal long-axis view was set at a reasonable "Nyquist limit of 77 cm/sec at 12 cm depth." The Settlement Agreement requires that the parasternal long-axis view be used to determine the level of claimant's aortic regurgitation when it is available. See Settlement Agreement §§ I.22. & IV.B.2.c.(2)(a).

Finally, we do not agree with claimant that she need only to prove that she suffered from at least moderate aortic regurgitation. As stated previously, to recover benefits for damage to her aortic valve, Ms. Lay must be diagnosed with moderate or severe aortic regurgitation and one of three complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(a). The only complicating factor at issue based on Ms. Lay's Green Form is pulmonary hypertension. The Settlement Agreement specifically requires "[p]ulmonary hypertension secondary to severe aortic regurgitation...." See id. § IV.B.2.c.(2)(a)I) (emphasis added). We are required to apply the Settlement Agreement as written.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had severe aortic regurgitation. Therefore, we will affirm the Trust's denial of Ms. Lay's claim for Matrix Benefits.